NOV - 3 2000

ENCLOSURE I

K001714

Premarket Notification (510(k) Mercury Medical Hyperinflation Bag System

**Summary of Safety and Effectiveness**

**Non-Confidential Summary of Safety and Effetiveness**
page 1 of 2
August 3, 2000

**Mercury Enterprises, Inc./Mercury Medical**
**11300 49th St. N.**
**Clearwater, Fl. 33762**
**Tel: (800) 237-6418**
**Fax: (727)572-4501**

**Official Contact:** **Ron Rupenski, CQE**
**QA/RA Manager**

**Proprietary or Trade Name: Mercury Medical Hyperinflation Bag System**

**Common/Usual Name: Manual Resuscitator**

**Classification Name: Class II, 73BZD, 21 CFR 868.5905**

**Device: Hyperinflation Bag System**

**Predicate Devices: SIMS Portex Inc., Hyperinflation Bag System - K970785**
**Meridian Medical, Hyperinflation Bag System – K942571**

**Device Description:**

**The Mercury Medical Hyperinflation Bag uses the same technology as the Meridian Medical Hyperinflation Bag, (K942571) and SIMS Portex, Inc., (K970785) Hyperinflation Bag with Manometer. The anesthesia bag is collapsed when not in use, and looks like a deflated balloon. It inflates only when a gas source is forced into the bag. It therefore is dependent on a compressed gas source**

**The device uses components similar to those in the Meridian and SIMS Hyperinflation Bag system. The bag will be latex free ranging in sizes of ¼, ½, 1, 2, and 3 liter bags. The bag bushing is made of thermoplastic materials, the rotating**

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**patient port and hyperinflation body consists of polycarbonate and the adjustment knob consists of LDPE. The Mercury Medical manometer, (K954486), is attached to the hyperinflation body. The gas enters the bag at the gas inlet. The inlet is a small projection designed to fit oxygen tubing. The bag system is attached to a standard hospital wall flowmeter for the means of gas flow. Control of gas escaping to prevent over inflating of bag is performed by means of bleed knob.**

**Intended Use:**

**Indicated Use: The Mercury Medical Hyperinflation Bag System is a pulmonary-assist device intended to provide controlled or assisted ventilation to patients.**

**Technical Characteristics: The device has the same technical characteristics as the predicate device marketed by SIMS Portex, Inc. and Meridian Medical.**

**Non-Clinical Data: Performance and specifications of the modified device are consistent with all requirements for this device type specified by ISO 5356-1: 1987 – Anesthetic and respiratory equipment-Conical connectors-Part 1: Cones and Sockets. ASTM F1054 – Standard Specification for Conical Fittings of 15mm and 22mm sizes.**

**Environment of Use: Hospital**

**Conclusions: The comparison to the predicate devices demonstrate that the proposed device are safe and effective and are substantially equivalent to the predicate devices.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Ron Rupenski
Mercury Medical
11300-49th Street North
Clearwater, FL 33762-4800

Re: K001714
Mercury Medical Hyperinflation Bag System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NHK

Dear Mr. Rupenski:

This letter corrects our substantially equivalent letter of November 3, 2000, regarding the Mercury Medical Hyperinflation Bag System. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NHK as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENVLOSURE B

**Indications for Use**



**510(k) Number:** K001714 (To be assigned)

**Device Name:**

**Intended Use:** The Mercury Medical Hyperinflation Bag System is a pulmonary assist device intended to provide controlled or assisted ventilation to patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001714

**Prescription Use** ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)